



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Keith R. D'ALESSIO et al.

Group Art Unit: 1772

Application No.: 09/430,289

Examiner: S. HON

Filed: October 29, 1999

Docket No.: 100497.02

For: POLYMERIC CONTAINERS FOR 1,1-DISUBSTITUTED MONOMER COMPOSITIONS

DECLARATION UNDER 37 C.F.R. §1.132

Director of the U.S. Patent and Trademark Office
Washington, D.C. 20231

#24
KLO
12-12-02

Sir:

I, Keith R. D'Alessio, a citizen of the United States, hereby declare and state:

1. I have a Bachelor of Science degree in Materials Engineering, which was conferred upon me by Drexel University in Philadelphia, Pennsylvania in 1986, and a Master's degree in Mechanical Engineering, which was conferred upon me by the University of Bridgeport in Bridgeport, Connecticut in 1990.
2. I have been employed by Closure Medical Corporation since 1997 and I have had a total of 16 years of work and research experience in plastics and medical devices.
3. I am a member of Alpha Sigma Mu, Pi Tau Sigma, the Society of Biomaterials, and ASTM International.
4. I have reviewed and am familiar with the disclosure and claims of the above-identified patent application, and the references cited in the Office Action mailed July 8, 2002.

5. In the July 8, 2002, Office Action, the Patent Office cites Maeda, U.S. Patent No. 5,909,976. The Patent Office argues that Maeda teaches a container for containing a cyanoacrylate, which comprises a fluororesin on the surface of the polyolefin container body that is treated with post-fluorination. The Office Action argues that the containers correspond to the containers and combinations of the presently claimed invention.

In response, I affirm that the containers and combinations of the presently claimed invention, comprising a polymeric resin matrix including at least one post-halogenated polymeric material, are different from the containers of Maeda. In particular, the post-halogenated polymeric materials of the presently claimed invention are different from, and exhibit different properties from, the treated fluororesin materials described in Maeda.

6. By way of explanation only, the structures disclosed in Maeda are different from the claimed structures. In particular, the structures of the claimed invention are post-halogenated or functionalized, i.e., a material that previously does not contain the halogen or functional species is exposed to a halogenation or functionalization treatment to introduce the species into the material. See, for example, instant claim 1. In contrast, the materials of Maeda are halogenated materials (fluororesins), which are subsequently exposed to an unspecified treatment process. See, for example, Maeda at col. 2, lines 41-42, col. 3, lines 62-64, and Example 1. These separate processes do not result in the same final product, at least because (1) the starting materials are different, and (2) the exact processing referred to in Maeda is not described in detail and Maeda teaches that the end results are different.

Furthermore, the properties of the resulting products of the claimed invention and Maeda are different. In particular, Maeda repeatedly emphasizes that the disclosed container includes a gas-impermeable layer, which prevents egress of stabilizer out of the cyanoacrylate composition and ingress of moisture into the cyanoacrylate composition. See, for example, Maeda at col. 2,

lines 31-44, and the detailed discussion at col. 3, lines 20-67, particularly lines 56-67. Maeda thus teaches that the containers must be gas-impermeable, preventing permeation both of stabilizer out of the container and moisture into the container.

With respect to the treatment of the fluororesin material, Maeda merely discloses that a subsequent treatment process may be required to help the fluororesin layer adhere to the underlying polyolefin layer. See. Col. 5, lines 15-22. Maeda discloses that such a treatment is conducted after the fluororesin layer is applied and dried. Col. 5, lines 21-22. Thus, Maeda specifically teaches that any such treatment is conducted on a material that is already fluorinated. Maeda then merely refers to the subsequent treatment processes as "treated by cooperation of Fluoro-Seal, Inc., to obtain a container main body." Col. 5, lines 24-25. However, Maeda does not describe what effects are provided by that treatment other than improved adhesion, and does not specify what that treatment is. See also Maeda at Example 1, where no specifics of the treatment process are provided.

In contrast, the claimed invention provides a container having a post-halogenated or functionalized material. The material of the claimed invention, while described as providing barrier properties, in fact is not gas-impermeable. Rather, the container of the claimed invention, including the post-halogenated or functionalized material, provides comparable moisture transmission rates as similar containers not including the post-halogenated or functionalized material. That is, the containers of the claimed invention provide comparable moisture transmission rates to conventional containers, such as the containers of Maeda Comparative Example 1, which Maeda specifically teaches are unsuitable for cyanoacrylate storage. The difference is that the post-halogenated or functionalized material of the claimed invention provides improved stability in a different mechanism from either the prior art or Maeda.

7. To further demonstrate the above-described differences, I and/or those under my direct supervision and control have conducted the following experiments, which were initially presented in my earlier-submitted Declaration dated June 21, 2002:

Ten otherwise identical 3 mL high density polyethylene bottles were selected. Five of the bottles were subjected to a post-fluorination treatment according to the claimed invention, while the other five bottles were not treated. Each of the bottles was tested to determine the moisture vapor transmission rate (MVTR) at conditions of 40°C and 75% relative humidity. The testing was conducted by filling the respective bottles with dessicant; placing the filled bottles in a heated testing chamber; and measuring a weight gain of the filled bottles over time, which weight gain corresponded to the moisture uptake of the dessicant in the bottles.

The results of the MVTR testing is set forth in Table I:

Table I

Specimen type	Average MVTR	Standard Deviation	Number specimens
Virgin HDPE	2.08×10^{-5} g/hr	0.14×10^{-5} g/hr	N=5
Post-fluorinated HDPE	2.03×10^{-5} g/hr	0.07×10^{-5} g/hr	N=5

The results in Table I indicate that the post-fluorinated HDPE bottles actually have substantially the same MVTR as virgin, i.e., non post-fluorinated, HDPE bottles. In contrast, Maeda teaches that virgin HDPE containers exhibit moisture vapor transmission rates that are too high for the containers to be used to contain cyanoacrylates. For example, col. 3, lines 19-48 and Comparative Example 1. Maeda describes that the problems of the prior art containers, i.e., vapor transmission, are addressed by providing a gas-impermeable layer. However, the above testing shows that the post-halogenation or functionalization treatment of the claimed invention does not provide the gas impermeable layer provided in Maeda. The experiment thus

demonstrates that the containers of the claimed invention are entirely different from the containers of Maeda.

8. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and/or imprisonment under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefore.

Date: 11/8/2002



Keith R. D'Alessio